

**REMARKS**

In the Office Action, claim 29 was rejected under 35 USC 112 as indefinite and under 35 USC 101 as reciting an improper method for not setting forth positive method steps. Claims 1, 22 and 26-30 were rejected under 35 USC 103(a) as allegedly obvious over Masuhara (US 2001/0002994, “Masuhara”) in view of newly cited Edwards (US 4,906,466, “Edwards”) and Bechert (US 6,984,392, “Bechert”). Claim 23 was rejected under 35 USC 103(a) as allegedly obvious over Masuhara in view of Edwards and Bechert and further in view of Pratt (US 4,849,223, “Pratt”). Claim 25 was newly rejected under 35 USC 103(a) over Masuhara in view of Edwards and Bechert and further in view of Sahota (US 2003/0181973).

The claims have been amended to remove improper multiple dependencies and for clarity. Claim 29 has been amended to recite positive method steps. Claim 1 has been amended to include recitation of elements in claim 15 as filed. Support for the amendments may be found throughout the application and claims as filed. No new matter is added.

**Request for Withdrawal of Improper Finality**

The Office Action contained multiple new grounds of rejection, which were not necessitated by Applicants’ amendments addressing the 35 USC 112(2) rejections raised in the prior Office Action. Applicants have not had an opportunity to respond to these newly raised issues, which could have been raised earlier in prosecution. Finality of the Office Action was therefore improper, and withdrawal of finality is respectfully requested.

Specifically, claim 25 was rejected for the first time over cited art. Additionally, the Edwards, Bechert and Sahota references were newly cited against claims 1, 22, 23, 25, and 26-30 in various rejections. Claim 29 was additionally newly rejected for not setting forth positive method steps. Applicants have not received a full and fair hearing on these issues, which were raised only in the current Office Action. MPEP 707 sets forth the standard for determining when an Office Action may properly be made final:

Before final rejection is in order a clear issue should be developed between the examiner and applicant. To bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the

references fully applied; and in reply to this action the applicant should amend with a view to avoiding all the grounds of rejection and objection. Switching from one subject matter to another in the claims presented by applicant in successive amendments, or from one set of references to another by the examiner in rejecting in successive actions claims of *substantially the same subject matter*, will alike tend to defeat attaining the goal of reaching a clearly defined issue for an early termination, i.e., either an allowance of the application or a final rejection.

... The applicant who is seeking to define his or her invention in claims that will give him or her the patent protection to which he or she is justly entitled should receive the cooperation of the examiner to that end, and not be prematurely cut off in the prosecution of his or her application. ...

The examiner should never lose sight of the fact that in every case the applicant is entitled to a full and fair hearing, and that a clear issue between applicant and examiner should be developed, if possible, before appeal.

(emphasis added).

In the prior response, Applicants amended the claims for clarity issues, as requested by the Examiner. These amendments were foreseeable, and did not alter the subject matter of the application. The new rejections and newly cited art (a shift in references over substantially the same subject matter) could have been presented in the first Office Action, and were not necessitated by Applicants' amendments.

It is respectfully submitted that Applicants should have a full and fair hearing on the newly raised issues in the current Office Action. Withdrawal of finality is respectfully requested.

#### The Rejections of Claim 29

Claim 29 was rejected under 35 USC 112, second paragraph as allegedly indefinite and under 35 USC 101 as reciting an improper method for not setting forth positive method steps. Claim 29 has been amended to set forth positive method steps. Withdrawal of the rejections of claim 29 is respectfully requested.

The Rejections Under 35 USC 103

Claims 1, 22 and 26-30 were rejected under 35 USC 103(a) as allegedly obvious over Masuhara (US 2001/0002994, “Masuhara”) in view of newly cited Edwards (US 4,906,466, “Edwards”) and Bechert (US 6,984,392, “Bechert”). Claim 23 was rejected under 35 USC 103(a) as allegedly obvious over Masuhara in view of Edwards and Bechert and further in view of Pratt (US 4,849,223, “Pratt”). Claim 25 was newly rejected under 35 USC 103(a) over Masuhara in view of Edwards and Bechert and further in view of Sahota (US 2003/0181973). These rejections are traversed.

As described previously, Masuhara does not teach or suggest the use of a preparation comprising an organic solvent, an organometallic titanium oxide precursor, and metal ions homogeneously dispersed in the preparation. As described in the present application, prior art titanium oxide coatings did not comprise homogeneous metal ions, but rather utilized admixed powders or salt-like compounds of micrometer dimensions (see paragraph 0008 and 0009). This is consistent with Masuhara’s description of the optional use of fine metal or metal salt particles, and of silver particles having a mean diameter of 2 micrometers (see paragraph 136 and example 5). Masuhara thus does not teach or suggest the homogeneous dispersion of metal ions in a preparation.

Further, Masuhara does not teach or suggest the formation of such a preparation that is a sol wherein the metal ions homogeneously dispersed and dissolved and are uniformly present in the coating after application to an implant.

Edwards, Bechert, Pratt and Sahota fail to rectify this deficiency in Masuhara. None of these citations teach or suggest the use of a sol to insure the fine homogeneity of metal ions in an implanted material coating.

Edwards was cited simply for the use of metal salts, and does not teach or suggest the use of a sol to provide homogeneous distribution of metal ions with a coating as claimed.

Bechert was incorrectly cited for allegedly teaching homogeneous distribution of silver in a matrix material. This is not the case. Bechert teaches the use of metals formed from aggregates of primary particles having an average particle size ranging from 10-100 um (see abstract and column 2, third paragraph). Bechert teaches the use of sintering to join the primary

metal particles in the aggregates essentially by “necks” formed between particles during heating, forming a highly porous framework. Thus Bechert does not teach or suggest the homogeneous dispersion or dissolution of metal ions in its coating as applied to an implant.

As previously set forth, Pratt simply describes the use of metallic silver coatings on titanium or tantalum oxide particles which are mixed in bone cements or deposited on catheters. Pratt does not teach or suggest any method of homogeneously distributing metal ions in a preparation that is a sol, as the metal in Pratt is provided on coated particles: Pratt utilizes a “slurry” of TiO<sub>2</sub> in his working example, demonstrating that his preparation is not homogeneous. See column 6. Furthermore, Pratt does not teach or suggest the use of organometallic titanium oxide precursors, which in the organic solvent preparation described here would not take the particle form used by Pratt. Pratt and Masuhara are thus not combinable, as they utilize fundamentally different forms of titanium having different properties, with Pratt utilizing or reciting a number of other non-titanium oxides.

Sahota is cited simply for the use of a plurality of titanium oxide coating layers on an implant. Nothing in Sahota teaches or suggests the use of a preparation that is a sol to provide homogeneous distribution of metal ions within any coating. Nor does Sahota teach or suggest the additional elements recited in claims 16-18.

Regarding the rejection of claim 29, Applicants dispute that Masuhara teaches the implantation of coated implants into a patient. Masuhara only deals with treatment of the external surfaces of oral devices. This is emphasized by the fact that Masuhara teaches light-activation of the coating, and the renewable aspect of his method, permitting re-activation by light treatment in the mouth or of removable oral devices. This is not possible with implanted surfaces within the body, which the claimed invention provides.

As none of the cited art teaches or suggests a method for obtaining the homogeneous distribution of metal ions using a preparation that is a sol used for coating an implant, all of the claim elements are not provided by the cited art. Obviousness has thus not been established. Withdrawal of the rejections under 35 USC 103(a) is respectfully requested.

**CONCLUSION**

**CONDITIONAL REQUEST FOR TELEPHONIC INTERVIEW**

Applicants respectfully submit that the claims are in condition for allowance. Should any issues remain after consideration of the above, the Examiner is requested to contact the undersigned at 858-228-7829 prior to the issuance of a subsequent action.

Respectfully submitted,

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